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Patent Docket P2026R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Jun Liu et al.  Serial No.: 10/813,483  Filed: March 29, 2004  For: HIGH CONCENTRATION ANTIBODY AND PROTEIN FORMULATIONS	Group Art Unit: Not Yet Assigned  Examiner: Not Yet Assigned  Confirmation No: Not Yet Assigned  CUSTOMER NO: 09157  <b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on  May 25, 2004  <i>T.E. Marrs</i>  Tom Marrs
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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of

allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in 37 CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because **a**) ☐ they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120 **and/ or** because **b**) ☒ this application was filed after June 30, 2003. Applicants are no longer required to submit copies of U.S. patents and U.S. patent application publications cited in information disclosure statements for all U.S. national patent applications filed after June 30, 2003

and for all international applications that have entered the national stage under 35 USC §371 after June 30, 2003 (**1276 OG 55**). Nevertheless, applicants stand ready to provide copies at the request of the Examiner.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

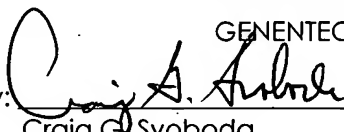
In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: May 25<sup>th</sup>, 2004

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FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P2026R1

Serial No.

10/813,483

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Liu et al.

Filing Date

29 Mar 2004

Group

Not Yet Assigned

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	2002/0045571 A1	18.04.02	Liu et al.			
	* 2	2003/0092607 A1	15.05.03	Carpenter et al.			
	* 3	5,608,038	04.03.97	Eibl et al.			
	* 4	5,994,511	30.11.99	Lowman et al.			
	* 5	6,037,453	14.03.00	Jardieu et al.			
	* 6	6,172,213	09.01.01	Lowman et al.			
	* 7	6,252,055	26.06.01	Relton, J.			
	* 8	6,267,958	31.07.01	Andya et al.			
	* 9	6,290,957	18.09.01	Lowman et al.			
	*10	6,329,509	11.12.01	Jardieu et al.			
	*11	6,682,735	27.06.04	Lowman et al.			
	*12	6,685,939	03.02.04	Jardieu et al.			
	*13	6,685,940 B2	03.02.04	Andya et al.			
	*14	6,699,472	02.03.04	Jardieu et al.			
	*15	6,723,833	20.04.04	Lowman et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	16	WO 92/17207	15.10.92	PCT			
	17	WO 93/04173	04.03.93	PCT			
	18	WO 97/04801	13.02.97	PCT			
	19	WO 99/01556	14.01.99	PCT			

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	20	Corne et al., "The Effect of Intravenous Administration of a Chimeric Anti-IgE Antibody on Serum IgE Levels in Atopic Subjects: Efficacy, Safety, and Pharmacokinetics" <u>J. Clin. Invest.</u> 99(5):879-887 (1997)
	21	Jones, A., "Analysis of Polypeptides and Proteins." <u>Adv. Drug Delivery Rev.</u> (10)29-90 (1993)
	22	Presta et al., "Humanization of an Antibody Directed Against IgE" <u>J. Immunol.</u> 151(5):2623-2632 (September 1, 1993)
	23	White et al. <u>Principles of BIOCHEMISTRY</u> , 3rd edition, McGraw-Hill company pps. 540 (1964)
	24	Zietkiewicz et al., "In Vivo Studies on the Action on the Tissue of the Osmolality of Parenterally Administered Drugs." <u>Grzyby Drozdopodobne.</u> (English Translation Attached) 23:869-870 (1971)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.